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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,538	07/19/2001	Josephine Egan	14014.0346U1	5705
23859	7590	09/27/2004	EXAMINER	
NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			JIANG, DONG	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/762,538	Applicant(s) EGAN ET AL.	
	Examiner Dong Jiang	Art Unit 1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-10,12-14,16-21,23,25-27,29-34,36,37 and 39-52 is/are pending in the application.
- 4a) Of the above claim(s) 39-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-10,12-14,16-21,23,25-27,29-34,36 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-3, 5-10, 12-14, 16-21, 23, 25-27, 29-34, 36, 37 and 39-52 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/16/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED OFFICE ACTION**

The request filed on 16 July 2004 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/762,538 is acceptable, and a RCE has been established. An action on the RCE follows.

Applicant's amendment filed on 16 July 2004 is acknowledged and entered. Following the amendment, claims 4, 15 and 35 are canceled, and claims 1-3, 9, 10, 12-14, 20, 21, 23, 25-27, 29-34, 36 and 37 are amended.

Currently, claims 1-3, 5-10, 12-14, 16-21, 23, 25-27, 29-34, 36, 37 and 39-52 are pending, and claims 1-3, 5-10, 12-14, 16-21, 23, 25-27, 29-34, 36 and 37 are under consideration.

#### **Withdrawal of Objections and Rejections:**

All objections and rejections of claims 4, 15 and 35 are moot as the applicant has canceled the claims.

The new matter rejection of claim 31 is withdrawn in view of applicant's amendment.

The rejection of claims 1-3, 5-10, 12-14, 16-21, 23, 25-27, 29-34, 36 and 37 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

The scope rejection of claims 1-10, 12-21, 23, 25-27 and 29, 30-37 under 35 U.S.C. 112, first paragraph are withdrawn in view of applicant's amendment.

The rejection for lack of written description of claims 1, 12, 23, 27, 31-34, and 36 under 35 U.S.C. 112, first paragraph are withdrawn in view of applicant's amendment.

#### **Objections and Rejections under 35 U.S.C. 112:**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-10, 12-14, 16-21, 23, 25-27, 29-34, 36 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for the recitation of “and a fragment of the preceding GLP-1 peptides” in lines 6-7. “A fragment of *one of* the preceding GLP-1 peptides” is suggested.

Claims 12, 23, 27, 31-34 and 36 are similarly indefinite.

Claim 3 is indefinite for the recitation “with the substance *in vivo*”. As the independent claim 1 is directed to an isolated population of cells, it is unclear how to get an “isolated population” *in vivo*, and therefore, the claim lacks sufficient method steps.

Claim 14 is similarly indefinite.

The remaining claims are rejected for depending from an indefinite claim.

**Rejections Over Prior Art:**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23, 26, 27, 30, 31, 36 and 37 remain rejected under 35 U.S.C. 102(b) as being anticipated by Eng, US 5,424,286, for the reasons set forth in the previous Office Actions, paper No. 10 and 15, and the one mailed on 1/13/04.

Applicants argument filed on 16 July 2004 has been fully considered, but is not deemed persuasive for reasons below.

At page 19 of the response, the applicant argues that the art cited by the Examiner does not teach contacting a population of non-insulin-producing cells with a substance for at least 24 hours, and that claims 23, 27, 31 and 36 are amended to recite “an amount of a substance effective to induce insulin production”, thus, even if a trace amount of a substance were present in the subject of the prior art, the art fails to teach contacting the cell with an effective amount of a substance to induce insulin production. This argument is not persuasive because the present claims, as written, do not distinguish themselves from the prior art in the active

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ingredient used and *method steps*. Thus, as addressed in the previous Office Actions, since the active ingredient and the method steps used are the same between the prior art and the present invention, the results or the consequences would be inherently the same, and there is no reason to believe that “an effective amount” for treating diabetes by the prior art and for inducing insulin production by non-insulin-producing cells of the present invention is different. [the prior art does not have to disclose the mechanism by which the method works in order to anticipate the claims, and mere discovery of the mechanism does not render the prior art method newly patentable. The Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on (*In re Best, Bolton, and Shaw*, (CCPA) 195 USPQ 430). Therefore, the burden is on applicants to show that the effective amount used in the prior art reference is ineffective to induce insulin production non-insulin-producing cells, and Applicants have not provided any factual evidence as to show such. Although the specification discloses a specific administration step of “by continuous infusion for at least 24 hours”, which is not taught by the prior art, the instant claims, as written, read on what the prior art reference teaches, and therefore, remain anticipated by the prior art.

Claims 23, 26, and 31 remain rejected under 35 U.S.C. 102(b) as being anticipated by Dupre (WO 95/31214), for the reasons set forth in the previous Office Actions, and for the reasons above.

Applicants present no further argument for this rejection in the response.

Claims 23, 26, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Edvell et al. (Experimental and Clinical Endocrinology & Diabetes, 1997, 105(4): A 36, provided by applicants).

Edvell discloses a method for testing the effect of GLP-1 on food intake and insulin release by injecting GLP-1 twice daily for two days. As such, the reference anticipates the present claims for the same reasons above.

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**Conclusion:**

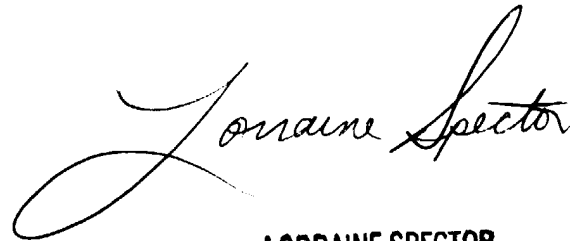
No claim is allowed.

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**Advisory Information:**

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

A handwritten signature in cursive script that reads "Lorraine Spector". The signature is written in black ink and is positioned above a printed nameplate.

**LORRAINE SPECTOR  
PRIMARY EXAMINER**

Dong Jiang, Ph.D.  
Patent Examiner  
AU1646  
9/3/04